DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Dear Investigator:

This letter is to inform you of the American College of Rheumatology (ACR)-sponsored International Myositis Assessment and Clinical Studies Group (IMACS) Outcomes Repository and to solicit your participation by providing data from your ongoing trial or clinical study in myositis. The ACR has supported IMACS' effort to prospectively validate the Preliminary Definitions of Improvement for Myositis. IMACS is establishing a database repository of core set measures and responses to therapy from a number of prospective therapeutic trials and natural history studies. These data will be pooled for analyses to prospectively validate the Preliminary Definitions of Improvement and to derive new response criteria for clinical trials. The repository will also be available to investigators with IRB- or ethics- committee approved protocols as a resource for other questions. The contribution of your data in the repository would qualify you for authorship on any resulting publications.

The IMACS database is a secured on-line Oracle database which is fully anonymized; only coded data is entered. Data may be entered into the IMACS database during the course of your clinical trial or study; only the investigators participating in your study would have access to the data until its conclusion and publication of results, at which time you would release the data to IMACS. Alternatively, data can be retrospectively entered into the IMACS database. A third way you can participate is to utilize your own database for your study, which can later be released to IMACS, but in this case you must provide a codebook of variables and a compatible format.

To participate in the IMACS Outcomes Repository, there are two major requirements: regulatory requirements and an agreement to contribute the minimum required data.

Regulatory Requirements:

For your study to be included in the IMACS Outcomes Repository, you must have ethics committee or institutional review board approval (IRB) for your study. All participating centers must hold a Federal Wide Assurance agreement and their IRB's must have approval by the US Department of Health and Human Services http://www.hhs.gov/ohrp/assurances/assurances_index.html and http://www.hhs.gov/ohrp/assurances/index.html):

There are 3 mechanisms for your study to be formally involved in the IMACS database repository:

A. For studies with local ethics committee or IRB approval, the local protocol can include or be amended on site to approve submission of data to the IMACS data repository. The data that is submitted would be coded, deidentified data in which the local investigators will maintain the code key, but not share this with IMACS study personnel. The consent form would include permission for use of the core set measures and other requested data in the IMACS Outcomes Repository, if required by the local IRB/ethics committee. You would need to submit a copy of your local IRB approval and consent form to us and we will obtain NIH IRB approval to include your trial/study in the IMACS Outcomes Repository.

B. We have a NIH IRB approved natural history of myositis protocol, which includes collection of the IMACS core set measures and establishment of the repository. This

protocol could be approved locally at your institution and your center can be approved for participation by the NIH IRB. This mechanism may be appropriate for one or a few centers participating in a study.

C. If your study has been completed and has been terminated (is no longer under IRB/ethics committee review), existing data could be submitted to the IMACS Outcomes Repository fully anonymized, with submission of a request for exemption to your local IRB/ethics office. Drs. Rider and Miller would then apply for receipt of the data through an exemption request with the NIH Office of Human Subjects Research. The disadvantage of this mechanism is that data cannot be linked to any medical records, and this limits the possibilities of correcting errors in data entry.

Under all of these mechanisms, your local officials (usually technology transfer office) will also determine whether a Data Transfer Agreement is required. If so, this will also be signed by the NIEHS technology transfer team.

Data Requirements:

A minimum data set that will be acceptable for entry into the IMACS data repository will include the following IMACS forms. We are willing to discuss this further with you if your trial has most of the required elements, but not all of them.
Here we provide the form number and link to the IMACS members' web site where you can view the specific forms (they may all be viewed at: https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=home.diseaseactivity).

1. Physician Global Assessment of Disease Activity (IMACS Form 02, found at https://dir-apps.niehs.nih.gov/imacs/docs/activity/phys_glob_act.doc).
2. Patient/Parent Global Assessment of Disease Activity (IMACS Form 03, found at https://dir-apps.niehs.nih.gov/imacs/docs/activity/pt_parent_glob_act.doc)
3. Manual Muscle Testing: MMT8 is the minimum dataset required. (IMACS Form 04, found at https://dir-apps.niehs.nih.gov/imacs/restrict/activity/mmt.pdf)
4. Functional Assessment Tool: Health Assessment Questionnaire or Childhood Health Assessment Questionnaire. (IMACS Form 05a or 05b, found at https://dir-apps.niehs.nih.gov/imacs/docs/activity/haq.doc and https://dir-apps.niehs.nih.gov/imacs/docs/activity/chaq.doc).
5. Muscle enzymes: at least 2 for each patient assessment in your study. (IMACS Form 06, https://dir-apps.niehs.nih.gov/imacs/docs/activity/lab_musc_enzy.pdf)
6. Myositis Disease Activity Assessment Tool: (IMACS Form 07a, 0-4 version 2, 2005, see https://dir-apps.niehs.nih.gov/imacs/restrict/activity/mdaat_2005_0-4_ver2.doc)
7. IMACS Trial Status (IMACS Form 12, found at https://dir-apps.niehs.nih.gov/imacs/restrict/forms/12trialstatusfinal.doc
8. IMACS Assessment of Study Outcomes: (IMACS Form 11, found at https://dir-apps.niehs.nih.gov/imacs/restrict/forms/11assessmentstudyoutcomes.pdf.
9. IMACS Core Patient Data: (IMACS Form 01, found at https://dir-apps.niehs.nih.gov/imacs/restrict/forms/01corepatientdata.doc
10. IMACS Trial Design Features: This form is completed one time for your study. https://dir-apps.niehs.nih.gov/imacs/restrict/forms/00trialdesigntool.doc
11. Repository Study Summary (IMACS Form 13, found at https://dir-apps.niehs.nih.gov/imacs/restrict/forms/13repositorystudysummary.pdf

This form is now part of the registration module in the on-line Oracle database to register your patients into the IMACS Outcomes Repository.

Extended Data: The following data are not required for inclusion in the IMACS data repository, but the option to enter this data into the IMACS Outcomes Repository will exist:

12. Childhood Myositis Assessment Scale (CMAS): (IMACS Form 05c, found at https://dir-apps.niehs.nih.gov/imacs/docs/activity/cmas.pdf)

13. Disease Activity Score: (IMACS Form 12, found at https://dir-apps.niehs.nih.gov/imacs/restrict/forms/dis_act_score.pdf)
14. We would like to discuss with you if your trial is collected Physician and Patient/Parent Global Damage and the Myositis Damage Index. These can be found at https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=home.diseasedamage
If a number of trials are collecting this data, we will include these damage measures in the repository.
15. We would like to discuss with you if your trial is collecting data on patient reported outcomes - either the SF-36 or the Child Health Questionnaire (CHQ-PF50), found at https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=home.patientoutcome.
If a number of trials are collecting this data, we will include this in the repository.

We greatly appreciate your considering collaborating in this important IMACS initiative to improve clinical assessments and ultimately the treatment of myositis subjects. Our next steps in this process would be to proceed with a collaboration agreement and approval of your study in the registry, followed by permitting your access to the on-line IMACS Outcomes Database on the IMACS website to enter data from your trial/clinical study. Please contact us with any questions on this proposal.

Sincerely,

Lisa G. Rider MD
Deputy Chief,

And

Frederick W. Miller, MD PhD
Chief,

Environmental Autoimmunity Group
NIEHS, National Institutes of Health
CRC 4-2332, MSC 1301, 10 Center Drive,
Bethesda, MD 20892-1301

Phone: (301) 451-6272
FAX: (301) 451-5588
Email: riderl@mail.nih.gov; milllerf@mail.nih.gov